REMARKS

The Final Office Action mailed June 26, 2007 has been received and carefully reviewed. All claims currently under consideration were rejected. The application is to be amended as set forth above. All amendments and claim cancellations are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

Applicants submit that there are clear legal and factual deficiencies in the rejections of the pending claims and that the Examiner has omitted one or more essential elements needed for proper and *prima facie* rejections. Each legal and factual deficiency is set out below in numbered sections captioned in bold font.

Claims 1-4, 6, 8-9, 12, 14-18, 20, 23, 25 and 27 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Zohmann (US Patent 6,558,353). Claims 5 and 21 are rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Zohmann in view of Kreuzer et al. (US Patent 5,116,323). Also, Claim 28 is rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Zohmann. The "Spinal Needle" as disclosed by Zohmann is as summarized in section *A. Personal Interview*, on p. 8, and section *E. 35 U.S.C. §102*, on p. 9 and p. 10 of Applicants' response ("Amendment") filed on purported February 1, 2007. Section *A. Personal Interview* and section *E. 35 U.S.C. §102*, are represented here for Examiner's convenience:

> *A. Personal Interview*
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> Applicants would like to thank the Examiner for the courtesy extended to the inventor N. Sandor Racz and applicants' undersigned representative during the personal interview of December 12, 2006. During the interview, the invention and outstanding rejections were discussed. Particularly discussed was the "flexible needle slidably mounted on a portion of the support needle" of, for example, applicants' instant independent claim 1, especially in comparison to the "sharp, hollow introducer component" of U.S. Patent 6,558,353 to Zohmann ("Zohmann") "used to puncture the skin". (Zohmann, column 4, lines 24-26). A commercial embodiment of the Zohmann device as well as a prototype of applicants' flexible spinal needle were displayed.
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> Furthermore, as identified by the Examiner,
>
> > Applicant described his invention and the differences between his invention and the prior art (Zohmann). Replacement drawings were filed

> 04/05/04. The trademark name in the claim language is to be amended by applicant. Applicant proposed some claim language and the Examiner suggested he file formally [in order] for the amendments to be considered.

E. 35 U.S.C. §102

Claims 1-4, 6, 8-9, 12, 14-18, 20, 23, and 25 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Zohmann. Applicants respectfully traverse the rejection.

It was thought that

> "Zohmann discloses a spinal catheter assembly having a needle 50 and [an introducer] 70 wherein the needle 50 has a non-cutting piercing pencil point and an opening 53 for providing feedback. The [introducer] is slidably mounted on the needle and shorter than the needle in order for exposing the pencil tip of the needle. The first and second attachment was considered to be the structure which provides the friction fit. The force absorbing structure is considered the nose 65 of the catheter. Zohmann further discloses a central stylet 30 mounted in the needle."

(Office action, p. 4).

As discussed at the interview, the introducer of Zohmann is not "flexible" as required by applicants' claims. As disclosed at column 4, lines 24-26, Zohmann's "sharp, hollow introducer component . . . is used to puncture the [patient's] skin", which could not be done with a flexible needle as required by applicants' claims. The introducer of Zohmann is "[inserted] at the puncture point", which could not be done with a flexible needle. (U.S. Patent 6,558,353 at column 2, line 39).

As described in applicants' Specification and discussed at the interview, a flexible needle is

> "characterized as a flexible conduit having distal and proximal ends. Preferred flexible needles have sufficient transverse flexibility to accommodate patient torso bending movement, whereby substantially to reduce a patient's awareness of the presence of the device. Flexible needles typically are made from medical grade plastic materials. For example, polyester shrink tube or similar materials may be used."

(Specification, underlining added, ¶ **[0018]**).

As further described in the Specification, applicant's flexible needle is

made of catheter material and has sufficient transverse flexibility to deform, *i.e.*,

> **[0036]** [t]he outermost layer of the assembly 10 is the flexible needle 15 itself. It preferably is approximately 23 g and about the length of a conventional spinal needle, although different diameters and lengths for use with different procedures is within the scope of the present invention. Conventional plastic catheter material may be used in its construction. The flexible needle material may be reinforced with a flat ribbon internal spring 45 (shown in FIG.5), an internal or external wire wrap, or other reinforcing structure. Alternative materials, and various materials in combination, also may be used to construct a flexible needle 15. Suitable catheter material produces a flexible needle 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from a patient. A flexible needle 15 desirably possesses sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation from the presence of a foreign body.

(Specification, underlining added, ¶ **[0036]**).

1. Claim Setting

The pending claims are directed, generally, to flexible spinal needle assemblies, and a flexible spinal needle and include independent claims 1, 16, 27, and 25, respectively.

Claim 1 requires, at least: "a **support** needle, and a **flexible** needle slidably mounted on a portion of said support needle."

Claim 16 requires, at least: "a **support** needle, and a **flexible** needle for inserting a distal end of said flexible needle through dura mater into a spine of a patient. "

Claim 25 requires, at least: "a **flexible** needle body comprising an elongated hollow tube, said flexible needle body configured to be slidably mounted on an exterior of a **support** needle."

Claim 27 requires, at least: "a **support** needle, and a **flexible** needle slidably mounted on a portion of said support needle," and further requires "said flexible needle has sufficient transverse flexibility to accommodate patient torso bending movement."

2. First Legal Deficiency - 35 U.S.C. § 102(e)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. §102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The Final

Office Action has failed to set forth under 35 U.S.C. §102(e), with the Zohmann reference, each and every element as required by independent claims 1, 16, 25, and 27.

The Examiner asserts that "Zohmann discloses a spinal catheter assembly having a needle 50 and a spinal catheter **[an introducer]** 70 wherein the needle 50 has a non-cutting piercing pencil point and an opening 53 for providing feedback. The spinal catheter **[introducer]** is slidably mounted on the needle and shorter than the needle in order for exposing the pencil tip of the needle. The first and second attachment was considered to be the structure which provides the friction fit. The force absorbing structure is considered the nose 65 of the catheter. Zohmann further discloses a central stylet 30 mounted in the needle." (Emphasis added, Final Office Action, p. 3).

While the "spinal catheter" terminology *purportedly* appears interchangeable with and includes similar meaning, the Zohmann reference actually discloses an **[introducer]**. (Zohmann, Col. 7, lns. 30-34). As further disclosed at column 8, lines 15-20, Zohmann's "sharp, hollow introducer [70] component a few centimeters in length is used to puncture the [patient's] skin, [allowing] a more blunt hollow needle [50] component... to delicately pierce the dura membrane", which skin puncture could not be done with a flexible needle as required by applicants' claims. On the contrary, a person of ordinary skill in the art would understand Zohmann's introducer to have at least the same, if not greater, *rigidity* relative to its needle. In this respect, Zohmann's introducer supports the needle. The claims, in contrast, require a **flexible** needle supported by a **support** needle, inapposite to Zohmann's introducer. Accordingly, the Examiner has failed to show the "flexible needle" as required to support a proper rejection. Therefore, the claims should be allowed.

3. Second Legal Deficiency – "Slight Modification"

In *Topliff v Topliff*, 145 U.S. 156 (1892), the court held that a prior patented device that performed a certain function did not anticipate a later invention designed for a different function even though the former device could be made to perform the function of the latter by "slight modification." The old device could not perform the new function without the modification, and the modification would not have been obvious to a person of ordinary mechanical skill unless he had the new function in mind.

In the instant case, Zohmann's "introducer" would have to be modified in length in order to be able to enter the dura mater, the introducer's beveled tip would have to be modified to permit resealing of the dura mater upon removal therefrom, and the introducer would have to be made more flexible relative to the spinal needle. Accordingly, all the claims should be allowed because the references do not teach or suggest each and every element required.

4. Third Legal Deficiency – "Claim Differentiation"

Within the specification, Applicants' have set forth their invention. In doing so, Applicants have presented many claim terms/elements that are distinct from one another. One element distinct from the other elements is the "flexible needle." Another element is the "support needle," which is also distinct from the each of the other elements. Applicants have consistently argued and presented in the specification that the flexible needle is flexible with respect to the support needle, also, *vis-a-vis,* the support needle is rigid with respect to the flexible needle, both being insertable into a patient's dura mater.

Claim differentiation doctrine is a specific application of the general principle that in construing the language in one claim, due consideration must be given to the language in other claims, *i.e.*, all dependent claims. It is in this regard, the claim language of the different claims determines the scope of the claims. Specifically, "where claims use different terms, those differences are presumed to reflect a difference in the scope of the claims." *Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305, 1310 (Fed. Cir. 2001). An interpretation of a claim that would render another claim in the patent superfluous is "presumptively unreasonable." *Whittaker Corp. v. UNR Industries, Inc.*, 911 F.2d 709, 711 (Fed. Cir. 1990). It is against this backdrop that Applicants clearly and consistently presented one claim element for a flexible needle and a different claim element for a support needle. The "flexible needle" element, including the various modifications thereto, is generally present in each of the independent claims and the "support needle" element is an additional element added to the claims, further, as provided for instance in claim 3, the flexible needle has a tip configured and arranged to provide a feedback signal to indicate dural puncture. The two elements are distinct from one another within each of the claims and represent different, albeit relative, scopes. Also, as taught by the description, the two elements are distinct from one another and represent different scopes. It is in this regard that a flexible needle is flexible relative to a support needle, and the support needle is rigid relative to the flexible needle, being sufficiently long enough to indicate dural puncture, thus the claims inherently require capability to be inserted into a patient's dura mater. The prior art shows an introducer 70 used to puncture the skin. However, Zohmann does not teach or suggest a flexible needle as is required by the claims. Accordingly, the elements of the claims and specification cannot be construed so broadly as to render another claim in the patent superfluous.

5. First Factual Deficiency

The Final Office Action misconstrues applicants' disclosure.

It was thought that "applicant's specification discloses that conventional catheter material may be used and that the "flexible" needle of applicants is "fairly stiff and has a sufficiently high tensile strength to maintain structural integrity". Thus, it appears that the "flexible" needle in the broadest interpretation is a relative term." (Final Office Action, p. 4).

As described in applicants' Specification and discussed at the interview, a flexible needle is "characterized as a flexible conduit having distal and proximal ends. Preferred flexible needles have sufficient transverse flexibility to accommodate patient torso bending movement, whereby substantially to reduce a patient's awareness of the presence of the device." (Specification, underlining added, ¶ **[0018]**). (See also claim 27).

As further described in the Specification, applicants' flexible needle is made of catheter material and has sufficient transverse flexibility, *i.e.*, "[c]onventional plastic catheter material may be used in [the flexible needles] construction. The flexible needle material may be reinforced with a flat ribbon internal spring 45 (shown in FIG.5), an internal or external wire wrap, or other reinforcing structure. Alternative materials, and various materials in combination, also may be used to construct a flexible needle 15. Suitable catheter material produces a flexible needle 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from a patient. A flexible needle 15 desirably possesses sufficient transverse flexibility to deform and accommodate patient motion to reduce irritation from the presence of a foreign body." (Specification, underlining added, ¶ **[0036]**).

The claim should be construed in light of the specification as interpreted consistent with the level of ordinary skill in the art practiced by the invention. *BOC Health Care, Inc. V. Nellcor Inc.*, 892 F.Supp. 598, 612 N.15, 614 (D. De. 1995), *Aff'd*, 98 F.3d 1357 (Fed. Cir. 1996)(unpublished). While the flexible needle may be fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, while in the body, and during retraction from a patient, it does not negate flexibility, particularly transverse flexibility, as the Final Office Action presupposes. The flexible needle, as disclosed in the specification and reinforced during prosecution, may geometrically deform, *i.e.*, flex, about its long axis to give a degree of flexibility as compared with a support needle in order to accommodate patient torso bending movement. This "flexibility" is a structural dimensional characteristic of the flexible needle which is coextensive with the other dimensions, e.g., compressional strength, hoop strength and torsional strength dimensional characteristics for supporting and maintaining structural integrity of this "conduit" during insertion, while in the body, and during retraction from a patient. Thus, the "flexible" needle is only relative in dimensional relationship to the support needle. In view of the foregoing, applicants request that the rejections be withdrawn.

6. Second Factual Deficiency

A claim limitation should not be read in isolation from the remainder of the specification and claim language. *See*, *BOC Health Care, Inc. V. Nellcor Inc.*, 892 F.Supp. 598, 614 (D. De. 1995), *Aff'd*, 98 F.3d 1357 (Fed. Cir. 1996) (unpublished). The Final Office Action interjects that a paperclip is an elongate tube. (Final Office Action, p. 4 and p. 5). To the contrary, a paperclip is not an elongate tube, it is a solid structure having no relevance with respect to the claims of the present invention. Moreover, the Examiner indicates that the paper clip is relatively rigid since it maintains its structure, and is relatively flexible since it can bend to accommodate more paper or be bent to a straight dimension. The Examiner comes by way of this example, however, by comparing the structure of the paper clip, irrelevantly, with its same structure. The present invention provides many distinct and different structures, *i.e.*, a flexible needle and a support needle, each having different relative characteristics. As such, the grounds for rejection are not supported by this rational, thereby providing another reason to withdraw the rejection.

7. 35 U.S.C. §103(a)

Claims 5 and 21 were rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Zohmann in view of Kreuzer et al. Also, Claim 28 is rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Zohmann.

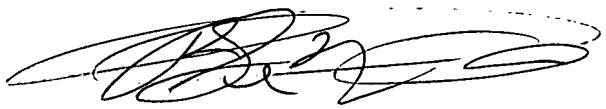
To establish a *prima facie* case of obviousness, there must be "a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 USPQ2d 1385 (2007). To establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S.Ct. at 1742.

Kreuzer does not remedy the inadequacy of Zohmann with respect to the "flexible needle" as required by applicants' claims. Zohmann does not teach or suggest the "flexible needle" as required by applicants' claims. Therefore, the rejection should be withdrawn.

CONCLUSION

Applicants submit that the Examiner's rejections are clearly erroneous and that the Examiner has not satisfied her burden. Accordingly, applicants respectfully request indication that the pending claims are allowable. If questions remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Enclosure: Supplement Information Disclosure Statement